K062856

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
100 Bayview Circle, Suite 6000
Newport Beach, CA 92660
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Colleen Boswell - Contact Person

DEC 13 2006

Date Summary Prepared: September 2006

Device Name:

- Trade Name – TF Rotary Nickel Titanium File
- Common Name – Endodontic Pulp Canal File
- Classification Name – File, Pulp Canal, Endodontic, per 21 CFR § 872.4565

Devices for Which Substantial Equivalence is Claimed:

- Sybron Endo, *Quantec Series 2000 Endodontic File*

Device Description:

The *TF Rotary Nickel Titanium File* is an engine (rotary) driven endodontic file intended for use in root canal preparation. The *TF Rotary Nickel Titanium File* is made from a single bar stock of nickel titanium that is machined and formed to create a single-piece file (handle, shaft and working portion).

Flutes are ground throughout the working portion, forming the cutting edges of the instrument and creating a tapered triangular cross-section. The file blank is heat annealed and the working portion is twisted to form helical cutting edges. The file is twisted instead of ground which enhances its flexibility and durability.

The *TF Rotary Nickel Titanium File* has a non-cutting (passive) tip and variable helical flute angle. The single-piece unit is intended to prevent separation of the handle from the shaft/working portion.

Intended Use of the Device:

The intended use of the *TF Rotary Nickel Titanium File* is for root canal preparation.

Substantial Equivalence:

The *TF Rotary Nickel Titanium File* is substantially equivalent to other legally marketed devices in the United States. The *TF Rotary Nickel Titanium File* functions in a manner similar to and is intended for the same use as the *Quantec Series 2000 Endodontic File* manufactured by Sybron Endo.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2006

Ormco, Corporation
C/O Ms. Colleen Boswell
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
100 Bayview Circle, Suite 6000
Newport Beach, California 92660

Re: K062856
Trade/Device Name: TF Rotary Nickel Titanium File
Regulation Number: 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EKS
Dated: September 22, 2006
Received: September 25, 2006

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

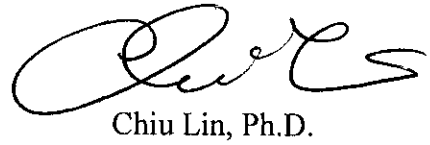
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062856

Device Name: TF Rotary Nickel Titanium File

Indications for Use:

The *TF Rotary Nickel Titanium File* is a rotary endodontic file designed for use in root canal preparation.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Anesthesiology, General Hospital,
Control, Dental Devices

(Division Sign-Off) K062856